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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT PAPER NUMBER

1772

DATE MAILED: 11/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,817

Applicant(s)

FUJIEDA ET AL.

Examiner

Christopher P Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to because the labeling of the figures is improper. The different views of the invention must be numbered in consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets. Each of the figures is a separate view and requires distinct Arabic numerals. The numbers must be simple and clear and must not be used in association with brackets, circles, or inverted commas (MPEP 608.02). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities: The disclosure is missing the cross-noting reference section in the first paragraph of the specification. The priority to the PCT and foreign priority must be listed in this section (MPEP 201.11 and 608.01(b)).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, the limitation "obtained by hydrogenating a block copolymer" in lines 7, 11, and 15 is indefinite because the limitation refers to a process of forming

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the block copolymer and structure in article claims is not defined by the process of making it. Therefore process limitations in article claims receive little patentable weight.

Claim 8 recites the limitation "layer (II-1)" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitations "layer (II-1)" and "layer (II-2)" in lines 2 and 6, respectively. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 14-15, both claims provide only limitations based on the use of the article, structure cannot be defined merely by stating an intended use. Therefore, use limitations in article claims receive little patentable weight.

Regarding all the claims, the use of parenthesis is prohibited in claim language except when referring to certain reference numbers on the drawings. The use of parenthesis is confusing because it is not understood if the limitations found within the parenthesis are claimed limitations or not. Also the breadth and definition of the claims must be determinable without reference to the specification or the drawings. The use of limitations such as "layer (II)" and "layer (II-1)" as well as copolymer (b) and copolymer (b1) is confusing because it is not understood what is being referred to. The should be listed

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as for example, "the second layer", and each copolymer or layer must have a distinguishing limitation, such as, the "isoprene-based copolymer" or "hydrogenated block copolymer containing isoprene". The claims must be rewritten to US Patent standards with these specific examples in mind in order to make the claims clear and understandable without referring to specifications or drawings.

Regarding claims 3 and 7, the thickness ratios are confusing and indefinite. It is not understood what the ratios actually are, the ratio in claim 3 could be written for example "940/60 - 980/20".

Regarding claim 2, the limitation that the tube is a dual layered tube, is determined to define a tube that comprises at least 2 layers. If the claim is meaning to define a tube with only 2 layers the claim must be written in closed language such as "consisting of".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4,13-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilmann et al (USPN 5,928,744).

Heilmann et al teach a multi-layered tube composed of at least two layers (Fig.1) wherein at least one layer of said layers is a layer made of a resin composition comprising 0-50 mass% of a polypropylene resin and 100-50% of a copolymer of hydrogenated styrene-butadiene-styrene, hydrogenated styrene-isoprene-styrene, such as SEBS or SEPS (col.6, 1.8-16) or a combination of SEBS and SEPS (col.8, 1.65-67). At least one layer of the remaining layers is a layer formed of a resin composition comprising 40-60 mass% of a polypropylene resin and 60-40 mass% of the above copolymer (col.6, 1.1-5 and col.8, 1.62-67). The first layer forms an intermediate layer or inner layer and the second layer forms the outer layer (Fig.1). Inner layer is determined to represent any layer inside the outer layer; therefore an intermediate layer is considered an inner layer. The first layer has a thickness of between 900-980 micrometers, and the second layer has a thickness of between 10-50 micrometers (col.6, 1.1-28). In the multi-layered tube styrene is the vinyl aromatic compound. The tube is a multi-

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layered tube for medical use, in particular as a fluid line in dialysis, infusion, or artificial feeding, primarily in connection with connectors or medical bags (abstract). Heilmann et al teach the tubes are in connection with medical bags; therefore inherently a medical device comprising the multi-layered tube recited above and a medical bag are connected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (USPN 5,928,744) in view of Strassmann (USPN 6,127,009).

Heilmann et al teach a three-layered tube comprising an intermediate layer comprising 0-50 mass% of polypropylene resin and 100-50 mass% of SEB or SEPS with a thickness greater than 900 micrometers and a second layer as the inner or outer layer comprising 50-100 mass% polyethylene resin and 50-0 mass% of SEBS or SEPS with a thickness of 10-50 micrometers and a third layer as the inner or outer layer comprising 40-60 mass% of a polypropylene resin and 60-40 mass% of the SEBS or SEPS with a thickness of 20-50 micrometers (col.6, 1.1-27 and col.5, 1.45-47). Heilmann et al fail to teach a second layer with polypropylene resin substituted for polyethylene resin. However, Strassmann teaches a multi-layered tube joined to a flexible polymer bag used in medical devices (Fig.1) in which polypropylene is used in making the tube rather than polyethylene because polyethylene had to be roughened to prevent the inside faces from sticking together when the inner layer of the bag was polyethylene (col.4, 1.32-35). If the second layer were used as the outer layer the polyethylene would also stick to other tubes when sanitized together. Substituting polypropylene for polyethylene when forming a flexible multi-

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layered tube for medical devices the processing steps of roughening are avoided, and furthermore the tube has even better transparency (col.4, 1.37-39). It is also notoriously well known in the art that polypropylene resins and polyethylene resins bond to themselves much better than to other resins, therefore substituting polypropylene for polyethylene in the second layer will improve the bond between the first and second layers. One of ordinary skill in the art would have recognized that polypropylene is substituted for polyethylene when forming flexible multi-layered tubes in order to avoid the processing steps of roughening and improve transparency of the tube and the bond formed between the layers, as taught by Strassmann.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to substitute polypropylene for polyethylene in the second layer of Heilmann et al, in order to decrease process steps, improve the transparency of the tube and to increase the bond strength between the layers of the multi-layered tube as taught by Strassmann.

7. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (USPN 5,928,744) in view of Takeuchi et al (USPN 5,264,488).

Heilmann et al teach all that is claimed in claim 1 and teach a hydrogenated block copolymer of SEBS, SEPS, or a combination of the two, which would inherently have a component weight ratio between 5/95 and 95/5 (col.8, 1.65-67). Heilmann et al does not appear to teach the percentage of styrene, the vinyl bond content of the isoprene and butadiene, or the percentage of hydrogenation. However, Takeuchi et al teach a medical device comprising a layer comprising 10-50wt% of a polyolefin resin and 1-89wt% of a hydrogenated block copolymer composed of a polymer block having a vinyl aromatic compound preferably styrene and a polymer block having a conjugate diene compound, which includes hydrogenated SBS and SIS. Takeuchi et al also teach specific characteristics of the hydrogenated block copolymer including that at least 90% of the block copolymer is hydrogenated because if the hydrogenation is less the block copolymer becomes deficient in heat resistance and weatherability (col.3, 1.41-49), which is needed in order to preserve the tube when subjected to sterilization. The vinyl bond content of the diene compound is in the range of 25-95mol% because if the content is less than 25mol% or more than 95mol% then the block shows a crystalline structure and assumes a resinous quality owing respectively to its separate components such as hydrogenated butadiene separates into ethylene and

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butylene, which would cause the block copolymer to lose its functionality (col.3, 1.16-25). The amount of the vinyl aromatic compound to be used in the block copolymer is not more than 35wt% because if this amount exceeds 35wt%, then the glass transition point of the block copolymer is unduly high and the dynamic properties of the component are unduly low (col.3, 1.8-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to make the hydrogenated block copolymers of Heilmann et al to the specifications of the hydrogenated block copolymers in Takeuchi et al in order to keep the glass transition point low, the hydrogenated diene compound from crystallizing and losing its functionality and make the tube efficient in weatherability and heat resistance to withstand sterilization, as taught by Takeuchi et al.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (USPN 5,928,744).

Heilmann et al teach all that is claimed in claim 1, but fail teach flexural modulus values for the polypropylene resin used to form the layers of the multi-layered medical tube. However, Heilmann et al uses all of the same block copolymers to

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form combine with the polypropylene resin as the applicant does to form the layers of the medical tube, and the tube is used for the same purposes. Routine experimentation in Heilmann et al would obviously produce similar values for the flexural modulus of the polypropylene resin because without similar values the tube using the same components as applicant would be either dramatically stiff or overly flexible when used as a medical tubing for a fluid line in dialysis, infusion, or artificial feeding.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to use, after routine experimentation, polypropylene resins with a bending flexural modulus as claimed, in order for the tubing to function correctly as a fluid line in dialysis, infusion or artificial feeding or a circuit for extracorporeal circulation.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hotta (USPN 4,588,777) and Tasaka (USPN 5,936,037).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 703-305-3440.

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The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

November 13, 2002



ALEXANDER S. THOMAS
PRIMARY EXAMINER